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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,677	07/27/2006	Chang-Ho Song	1012679-000125	8471

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/587,677	SONG ET AL.	
	Examiner	Art Unit	
	DEBORAH A. DAVIS	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7-8-08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-27-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-11 and 14-16 in the reply filed on July 8, 2008 is acknowledged. Claims 12 and 14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 8, 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition for the treatment of allergic diseases comprising the herbal extract of claim 1, does not reasonably provide enablement for a pharmaceutical composition for the "prevention" of allergic disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors regarding undue experimentation have been summarized in In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The State of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The claims are drawn to a pharmaceutical composition for the prevention or treatment of allergic diseases comprising the herbal extract of claim 1 as an active ingredient.

Breadth of the claims: The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification.

Guidance of the Specification and Existence of Working Examples: The specification describes a working examples where peritoneal mast cells of rats were pretreated with the mixed extract of Houttuynia cordata and Rubus coreanus, which is the herbal extract of claim 1. The results showed the inhibition of the release of histamine from the mast cells (see page 7 and Example 3). Also the herbal extract was shown to reduce coetaneous lesions in rats (see specification pg 35, e.g.). The specification does not show any examples of the prevention of allergic diseases when

being treated with the combined herbal extract of Rubus coreanus and Houttuynia cordata. Although the M.P.E.P does not require the applicant to provide examples, however, there must be sufficient teaching in the absent of examples in the specification to enable one of ordinary skill in the art at the time the invention was made to use the invention commensurate in scope with the claims.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable. There is no prior art that describes that the instantly claimed herbal extract comprising Rubus coreanus and Houttuynia cordata to prevent allergic diseases; neither has applicant demonstrated it through the instant specification through teaching or example. Thus, it would require undue experimentation to practice the claimed invention because the instant specification does not offer guidance. Please note that the term "prevention" is an absolute definition which means to stop from occurring and, thus requires a higher standard for enablement than does "treating", especially since it is notoriously well accepted in the medical art that the vast majority of afflications/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes).

In view of the breadth of the claims and the lack of guidance in the specification as well as the unpredictability of the art, it would have required an undue amount of experimentation. Therefore the instant clams are not considered to be fully enabled by the instant specification.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 recites a use of an herbal extract without setting forth proper process steps. Therefore it is unclear as to whether applicant intends to claim a method or a composition. Therefore, the claims will be examined as composition claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 are rejected und 35 U.S.C. 101 because the claimed recitation of a use without setting forth any steps involved in the process results in an improper definition of a process, i.e., results in a claim which is not a proper process claims under 35 USC 101. 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App.1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131,149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-11 and 14-16 are rejected under 35 U.S.C. 102(a) as being anticipated by (KR 2003/057509 A).

The claims are drawn to an herbal extract having inhibitory activities against the degranulation and histamine release of mast cells, which is obtained by extracting Houttuynia cordata and Rubus coreanus with water or organic solvent. The reference of Su Jeong anticipates the instant claims by disclosing an herbal extract comprising houttuynia cordata, folium Mori, and rubi Fructus (unripened fruit of rubus coreanus) as active ingredients. The herbal extract is obtained by water extraction (paragraph 5, e.g.). The herbal extract is a health food and a crude drug and therefore qualifies as a pharmaceutical, as claimed. The herbal extract comprises of the same ingredients as claimed and therefore would inherently provide the functional effects as recited in the instant claims.

Therefore the cited reference is deemed to anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su Jeong.

The reference of Su Jeong beneficially teaches a health food and crude drug in comprising an herbal extract that includes Houttuynia cordata, folium Mori, and rubi Fructus (unripened fruit of rubus coreanus) as active ingredients. The herbal extract is obtained by water extraction (paragraph 5, e.g.). The herbal extract is a health food and a crude drug and therefore qualifies as a pharmaceutical, as claimed. The herbal extract of the cited reference are the same ingredients as claimed and therefore would intrinsically provide the functional effects as recited in the instant claims.

The teaching of Su Jeong are set forth above but is silent with respect to the ratio of Houttuynia cordata to rubi Fructus (unripened fruit of rubus coreanus).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an herbal extract comprising the claimed ratios and further comprising Mori folium as an active ingredient based on the beneficial teachings that the herbal extract is a health food and crude drug. The adjustment of particular conventional working conditions (e.g. to determining suitable ratios of rubis Fructus to

Houttuynia cordata) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of the evidence to the contrary.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
October 2008

/Christopher R. Tate/
Primary Examiner, Art Unit 1655